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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/134,417	08/14/98	ROSS D	22789-XS

HM12/1130

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EXAMINER	
KIM, V	
ART UNIT	**PAPER NUMBER**
1614	8

DATE MAILED: 11/30/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/134,417	Ross et al
Examiner	**Group Art Unit**
Vickie Kim	1614

☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-26* is/are pending in the applicat

Of the above, claim(s) *6-9, 11-20, 22, 25, and 26* is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-5, 10, 21, 23, and 24* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 3

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Response to Arguments

1. Applicant's election filed on October 1,1999 with traverse is acknowledged. Applicant's traverse the restriction/election requirement on the grounds that there would be no burden in searching the entire groups. This argument is persuasive on Group I & II of the restriction requirement because restriction requirement is withdrawn due to reasonably searchable, related subject matters within the range where this examiner can bear the burden. **Supplemental restriction requirement is followed below.** The election of species requirement is maintained because of the search of the entire groups in the non-patent literature (a significant part of a thorough examination) would be burdensome. Therefore, the requirement is still deemed proper.

******Supplemental action*****

Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10, 21, and 23-24 are, drawn to a method of treating vision disorders and memory disorders , comprising administering an effective amount of a pipecolic acid derivative, classified in class 514, subclass 317+.

II. Claims 11-20, 22 and 25-26 are, drawn to a composition containing a pipecolic acid derivative , classified in class 514, subclass 317, 318, 12, 330, 248+(various depending on the structure of the species)

3. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In this instant case the products (compositions) as claimed may be used in a plurality of patentably distinct processes of use, as evidenced by 1) the several different uses claimed (groups I and II above), and by previously issued US patents to the subject compounds, which patents teach using the subject compounds as neurogenic agents, or immunosuppressant.

4. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II. A reference which anticipates the invention of Group I would not render the invention of Group II obvious, absent ancillary art, restriction for examination purposes as indicated is proper.

Election of Species

5. **The restriction and election species requirement on the grounds that there would be burden in searching the entire groups, as not all the groups would be classified together. Furthermore, even if there were unity of classification, the search of the entire groups in**

the non-patent literature(a significant part of a thorough examination) would be burdensome.

a. Election of species requirement is following below.

b. This application contains claims directed to the patentably distinct species of the claimed invention: the various species encompassed by formulas I ,II and III individually.

6. Claims 1-26 are generic to a plurality of disclosed patentably distinct species comprising various pyrrolidine derivatives. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

7. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

8. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Election acknowledged

9. Election is acknowledged. Invention (Group I-with the elected species; compound of 3-phenylpropyl(2s)-1-(3,3-dimethyl-2-oxopentanoyl)hexahydro-2-pyridinecarboxylate) is subjected to the examination, and non-elected group and species are withdrawn from consideration.

Detailed action

Status of Application

10. Claims 1-5,10, 21, and 23-24 are pending.

11. Claims 6-9, 11-20, 22 and 25-26 are withdrawn from consideration.

Specification

12. The disclosure is objected to because of the following informalities: The table B, C and D has to be relabeled as "figure" and should be filed in separate sheets. If there is any description, the brief description of the drawings must be added into the specification.

Appropriate correction is required.

Double Patenting

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

a timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. a terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 1-5, 10, 21 and 23-24 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 5,798,355 in view of Behl (1997) and Bourne et al (1998 march).

US'355 teach a method of treating a neurological disorder comprising administering an effective amount of compound of generic formula including elected species:3-phenylpropyl(2s)-1-(3,3-dimethyl-2-oxopentanoyl)hexahydro-2-pyridinecarboxylate: See claims 1 and 7, especially 12th compound. The term "Neurological disorder" encompass various diseases such as peripheral neuropathies , and neurological disorders relating neurodegeneration(e.g. Alzheimer's disease) as stated in the cited reference.

Claims differ because they call for vision and memory disorders rather than peripheral neuropathies and neurological disorders.

However, it would have been obvious to one of ordinary skill in the art to include vision and memory disorders in the said neurological disorders when US'355 is taken in view of Behl(1997) and Bourne et al (3/1998) .

First, Behl teach loss of memory is a characterized in neurodegeneratative disorder in the Alzheimer's patient.

Second, Bourne et al (3/1998) teach vision impairment and disorders are occurs in association with peripheral neuropathy.

One would have been motivated to treat vision and memory disorders using the said compound because peripheral neuropathies and neurological disorders relating neurodegeneration(e.g. Alzheimer's disease), are characterized by vision and memory disorders and eventually improve the disease state of vision and memory related diseases.

One would have been motivated to combine these references because they are drawn to same technical field and pertinent to the problem with which applicant is concerning. MPEP 2141.01(a).

Conclusion

15. All the pending claims are rejected.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *Vickie Kim* whose telephone number is **(703)305-1675.**

Vickie Kim, patent examiner

November 18, 1999

WILLIAM R. A. JARVIS
PRIMARY EXAMINER
ART UNIT 1614